IN THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF TENNESSEE NASHVILLE DIVISION

RUTH SMITH, Individually and as Widow for the Use and Benefit of Herself and the Next of Kin of RICHARD SMITH, Deceased,	)	**Case #: 3:05-00444**
	)	**Judge Trauger**
Plaintiff,	)	
-against-	)	
PFIZER INC., PARKE-DAVIS, a division of Warner-Lambert Company and Warner-Lambert Company LLC, WARNER-LAMBERT COMPANY, WARNER-LAMBERT COMPANY LLC and JOHN DOE(S) 1-10,	)	
Defendants.	)	

MEMORANDUM IN SUPPORT OF PLAINTIFF'S MOTION FOR PRIOR APPROVAL TO EXCEED THE THREE-EXPERT WITNESS LIMITATION UNDER LOCAL RULE 39.1(c)(6)(a), AND FOR EXPRESS PERMISSION TO BRING COMPUTERS AND ELECTRONIC MEDIA INTO THE COURTROOM FOR USE DURING THE TRIAL OF THIS ACTION UNDER LOCAL RULE 83.02(a)(2) AND PRACTICE AND PROCEDURE MANUAL RULE V(M)

Plaintiff Ruth Smith, as the Widow for the use and benefit of herself and the next of kin of Richard Smith, deceased, by and through her attorneys, hereby moves this Court for an order granting Plaintiff prior approval to exceed the three-expert-witness limitation under Local Rule 39.01(c)(6)(a), due to a myriad of issues in this complex products liability action which require various expert opinions. Further, Plaintiff requests express permission from this Court, under Local Rule 83.02(2) and this Court's Practice and Procedure Manual V. Trial Procedures (M) Courtroom technology, to bring computers and electronic media into the courtroom for use during the trial of this action.

PRELIMINARY STATEMENT

Plaintiff requests prior approval to exceed the three-expert limitation under Middle District of Tennessee Local Rule 39.01(c)(6)(a), which provides:

> No more than three (3) witnesses shall be called in any case to give expert testimony as to any matter, or to impeach or sustain the character of a witness, absent prior approval of the Trial Judge.

Plaintiff is requesting clarification from this Court whether the local rule is interpreted by this Court as allowing no more than three expert witnesses on any single relevant issue in this case, or whether the three-expert-witness limitation applies to the total number of witnesses a party may call in a case, irrespective of the number of issues that require expert opinion to prove. In either case, Plaintiff's claims in this complex products liability litigation are multi-faceted, and she requests permission to exceed this limitation as Plaintiff will require the expert opinion of more than three experts, all of whom have expertise in different scientific, regulatory, psychological and other fields, in order to adequately prove her claims.

In this case, Plaintiff must prove proximate cause, which will entail demonstrating that Neurontin has the capacity to cause suicide (general causation) and that Neurontin was a substantial factor in causing the suicide of Plaintiff's decedent Richard Smith (specific causation). Plaintiff is also claiming in this case that Defendants had notice and should have been alerted to pre- and post-marketing "safety signals" that indicated Neurontin could cause adverse mood and behavior and increase the risk for suicide. Moreover, Plaintiff requires expert testimony to prove her failure-to-warn claim (i.e., that Defendants failed to warn of Neurontin's risk of suicidality). Furthermore, Plaintiff claims that Defendants willfully and recklessly promoted Neurontin for "off-label" uses (i.e., uses not approved by the FDA) and that Defendants fraudulently concealed the risks of suicidality. Finally, Plaintiff requires an opinion

from an expert in the field of marketing (i.e., Kip King, J.D., Ph.D.) to testify, *inter alia*, that Defendants' off-label promotion influenced the prescribing practices of physicians, including decedent's physicians in this case.

In regard to Plaintiff's request to permit counsel's use of computers and electronic media in the courtroom, Defendants have produced more than three million pages of documents as well as databases comprising several gigabytes of information. *See* Keith L. Altman Declaration ¶ 2. For greater efficiency, Plaintiff intends to present evidence during the trial using electronic means. In order to accomplish this, it is necessary for Plaintiff to have computer equipment available in the courtroom. This has been the practice of Plaintiffs' counsel in both of the two previous Neurontin trials that have taken place. Plaintiff also intends to introduce testimony by video deposition for certain witnesses. This video is played through a computer, necessitating Plaintiff's use of computers in the courtroom.

ARGUMENT

A. Plaintiff Requests Permission to Exceed the Three-Expert Limitation

1. Plaintiff Requests Permission to Allow the Expert Testimony of Dr. Michael Trimble and Dr. Cheryl Blume to Prove the General Causation And Failure-to-Warn Claims.

To prove general causation proof in this case, Plaintiff requests permission to allow the testimony of two experts, both of whom have previously appeared and provided testimony before Judge Patti B. Saris at a *Daubert* hearing in the multidistrict litigation in the District of Massachusetts.

Dr. Michael J. Trimble is expected to provide the requisite expert testimony on general causation, *inter alia*, that Neurontin has the biological plausibility to cause adverse changes in

mood and behavior that predictably lead to suicide. *See In re Neurontin Mktg., Sales Practices & Prods. Liab. Litig.*, 612 F. Supp. 2d 116, 123-24 (D. Mass. 2009).

As noted by Judge Saris, who denied Defendants' *Daubert* challenge to Dr. Trimble's expert general causation opinion, Dr. Trimble's credentials were not challenged by Defendants:

> Dr. Michael Trimble is Professor Emeritus of Behavioral Neurology at the Institute of Neurology and Honorary Consultant Physician to the Department of Psychological Medicine at the National Hospital for Neurology and Neurosurgery, both located in London. (Declaration of Professor Michael Trimble, M.D., in Relation to Neurontin Causing Negative Mood and Behavioral Alterations, including Suicidal Behavior, in Treated Patients, at 4-5) (Pls.' Ex. 8) (hereinafter "Trimble Rep.") He holds multiple degrees and has authored or edited several books addressing the interface between neurology and psychiatry, especially in the field of epilepsy and its treatment. (Id.) Dr. Trimble has also published over 120 peer-reviewed papers on similar topics. (Id.) Plaintiffs tout him as the "world's foremost expert with substantial clinical experience regarding antiepileptic drugs' effects on mood and behavior." (Pls.' Mem. in Opp'n 47) (Docket No. 1191.) Moreover, Dr. Trimble has specifically studied and written about Neurontin. In fact, in 1995 and 1996, he was hired by Warner Lambert to investigate the relationship, if any, of Neurontin to psychosis and behavioral disturbances. (See Michael Trimble, Psychosis with Gabapentin (Neurontin), May 20, 1995 (Pls.' Ex. 17); Michael Trimble, Behavioural Disturbance with Gabapentin, Report for Parke, Davis, & Company) (Pls.' Ex. 18.)) Defendants do not challenge his qualifications.

614 F. Supp. 2d at 124.

Plaintiff submits that she also requires the expert opinion of Dr. Cheryl Blume, an expert on Food and Drug Administration and regulatory issues, to prove general causation claims and to demonstrate that Defendants failed to perform the proper pre- and post-pharmacovigilance. Dr. Blume has opined, *inter alia*, that there were adverse events, case report data, and *in vitro* studies reflecting Neurontin's actions on neurotransmitters in the brain (e.g., serotonin, norepenephrine) that demonstrate that Defendants had notice, or should have been on notice had they performed the requisite pharmacovigilance, that there were "safety signals" which indicated that ingestion of Neurontin increased the risk for mood and behavioral disturbances, including suicidality.

Dr. Blume has extensive FDA regulatory experience, as noted by Judge Saris, who denied Defendants' *Daubert* challenge to Dr. Blume:

> Dr. Cheryl Blume holds a Ph.D. in pharmacology and toxicology from the West Virginia University School of Medicine. (See Curriculum Vitae of Cheryl Blume, Ph.D. (Pls.' Ex. 116.)) She has extensive experience in the evaluation of safety information of pharmaceutical products; for the past twenty-five years, Dr. Blume has worked with pharmaceutical companies to prepare new drug applications and supplemental documents for submission to the FDA. In this role, Dr. Blume has worked on at least 150 submissions to the FDA for more than fifty different drugs. (Blume Decl. ¶ 3) (Pls.' Ex. 102.) She has been involved in collecting and evaluating post-marketing adverse event reports, as well as the design of studies to assess safety signals after a drug has been approved. (Blume Rep. ¶ 3.)

614 F. Supp. 2d at 161, 162.

Dr. Blume will provide expert opinion that Defendants failed to reasonably warn healthcare professionals about the association of Neurontin with psychobiologic adverse events, including suicidal behavior. Dr. Blume sets forth numerous proposed labeling changes Defendants should have proposed to the FDA.

> Plaintiffs' experts point to the adverse event and case report data as real-world evidence to back up their theory that Neurontin increases the risk of suicidality in its patients. As summarized by Dr. Blume: "While these events do not prove that Neurontin causes suicidal behavior, they do demonstrate, in conjunction with the vast numbers of post-marketing events, that Neurontin can be associated with suicide-related behavior."

614 F. Supp. 2d at 160, 161.

2. Plaintiff Requires the Expert Testimony of Dr. Sander Greenland to Rebut Dr. Gibbons' General Causation Opinions Regarding the FDA Meta-analysis and Gibbons Opinions Regarding Neurontin.

Plaintiff will also require the expert testimony of a Dr. Sander Greenland, a statistician and epidemiologist, who will opine that the FDA used sound statistical methodologies in reaching their conclusions that Neurontin increases the risk of suicidality. Furthermore, Dr. Greenland will testify as a rebuttal witness that the opinions of Defendants' expert Dr. Robert

Gibbons are not scientifically sound and that Dr. Gibbons' paper on the risk of suicidality associated with the use of anticonvulsants has serious methodological flaws. Judge Saris permitted Dr. Greenland to submit an expert report and rebut Dr. Gibbons' opinion:

> Dr. Greenland is Professor of Epidemiology at the UCLA School of Public Health and Professor of Statistics at the UCLA College of Letters and Science. His co-authored textbook Modern Epidemiology is used in numerous schools of public health and medicine and has been cited in peer-reviewed journals and the Federal Judiciary Center's Reference Manual on Scientific Evidence. Dr. Greenland has authored hundreds of peer-reviewed articles and has served in leadership positions on both the Society for Epidemiologic Research and the American Statistical Association, both the largest societies in the world in their fields. (See Expert Report of Sander Greenland, Oct. 19, 2007, at 3-6) (Pls.' Ex. 89.)

614 F. Supp. 2d at 140.

3. Plaintiff Requires Dr. Ronald Maris, Who Performed A Psychological Autopsy to Prove Specific Causation, That the Ingestion of Neurontin Was a Substantial Factor in Richard Smith Committing Suicide.

Dr. Ronald Maris is an experienced suicidologist, and Defendants did not dispute his credentials in their *Daubert* motion on specific causation in this case. *In re Neurontin Mktg., Sales Practices & Prods. Liab. Litig.*, No. 1:05-cv-11515-PBS, 2009 U.S. Dist. LEXIS 118006 at *63 (D. Mass. Aug. 14, 2009). Judge Saris noted Dr. Maris' qualifications in her decision:

> Dr. Maris holds a Ph.D. (as opposed to an M.D.) and is a Distinguished Professor Emeritus at the University of South Carolina where he holds appointments in both the Psychiatry and Family Medicine departments. He created and directed the Suicide Center at the University of South Carolina and currently teaches courses in suicide prevention. He has investigated thousands of suicides, has written twenty books on suicide, and publishes on the topic in peer-reviewed scientific journals.

Id.

Dr. Maris utilized a generally accepted methodology, a psychological autopsy, in order to analyze what led to Richard Smith's suicide in this case. *Id.* at 65-67. Judge Saris noted that Dr. Maris essentially provides a seven-part expert opinion:

> First, the psychopharmacologic properties of gabapentin/Neurontin are suicidogenic;
>
> Second, Richard Smith had clearly been ingesting Neurontin from March 9, 2004 until his death on May 13, 2004;
>
> Third, Richard Smith had several suicidogenic serious adverse events ("SAEs" or "side effects") resulting from taking Neurontin;
>
> Fourth, apart from taking gabapentin Richard Smith was only moderately suicidal, a condition that he had been able to cope with prior to ingesting Neurontin on 3/9/04 and thereafter;
>
> Fifth, Richard Smith had several personal characteristics that are known to be protective from suicide . . . .;
>
> Sixth, Richard Smith did not kill himself because of his chronic physical pain;
>
> Finally, it is more likely than not, if Richard Smith had not taken Neurontin on March 9, 2004 and thereafter, that he would not have committed suicide.

Id. at 64-65.

Plaintiff requires the expert opinion to prove specific causation in that Richard Smith's ingestion of Neurontin was a substantial factor in his committing suicide. Judge Saris held that Dr. Maris' expert opinion was admissible on this issue:

> In sum, this Court concludes that Dr. Maris' specific causation testimony is based upon sufficient facts and data and is the product of reliable principles and methods which have been applied reliably to the facts of the case. See Fed. R. Evid. 702. It is very relevant to the task at hand and Dr. Maris is highly qualified to speak on these matters. Accordingly, his specific causation testimony is admissible.

Id. at 78. 79.

4. The Expert Opinion of Dr. Charles King, III Is Required to Prove Defendants' State of Mind and Plaintiff's Claim That Defendants Recklessly Promoted/Marketed Neurontin Off-label for Uses Not Approved by the FDA And to Prove Plaintiff's Fraudulent Concealment/Suppression Claim.

Judge Saris, in her May 26, 2009 Order, succinctly described the heightened duty to warn that a pharmaceutical manufacturer bears when it engages in off-label marketing of a drug:

> Based on the reasoning of this caselaw, the Court concludes that a manufacturer of a pharmaceutical has a duty to disclose to physicians and patients material facts about the risks of the drug, particularly when it is engaged in off-label marketing for uses not approved by the FDA, if it knows that the plaintiff and/or his prescriber does not know or cannot reasonably discover the undisclosed facts.

In re Neurontin Mktg., Sales Practices & Prods. Liab. Litig., 618 F. Supp. 2d 96, 110 (D. Mass. 2009) (emphasis added).

Plaintiff's marketing expert Dr. Charles King, III, provides expert testimony relevant to Defendants' breach of their duty of care to perform adequate pharmacovigilance and Defendants' actions to reap the benefits of illegally promoting Neurontin for off-label uses. Dr. King provides expert opinions regarding the fact that Defendants' breach of their duty of care was intentional, that they had a plan, had a motive and had the opportunity to avoid their duty of care. Dr. King opined regarding Defendants' marketing for off-label uses:

> Warner-Lambert estimated that the "ultimate" sales potential for Neurontin over the life of its patent was on $500 million because of the limited adjunctive use for which it had been approved. To expand the market for Neurontin, Warner-Lambert developed a "publication strategy." Its goal was "to disseminate the information [about Neurontin's potential use for psychiatric disorders, including bipolar and mood and anxiety disorders] as widely as possible through the world's medical literature" as a means of generating excitement in the market and stimulating off-label prescriptions despite the lack of FDA approval. Warner-Lambert calculated that this strategy would avoid the costly and time-consuming clinical trials required for FDA approval.

Expert Report of Charles King III, annexed hereto as Exhibit A, at 11.

Dr. King opines concerning the insidious details of how Defendants were well aware that they were thwarting the FDA approval process and intentionally breached their duty of care in the promotion of Neurontin for off-label uses:

> In the case of Neurontin, it was crucial for Warner-Lambert and allegedly Pfizer to maintain that these expenditures were for education, not promotion, so that it could evade legal constraints on its marketing activities.

Exhibit A at 24.

Dr. King further opined concerning Defendants' intentional breach of their duty of care to off-label users:

> After evaluating the potential markets for other clinical uses, such as treatment of bipolar disorder, painful diabetic neuralgia, and chronic pain, Warner-Lambert calculated that seeking FDA approval would not be worthwhile because of the expense of clinical trials, the short remaining patent life for Neurontin, and potential adverse impact on the sales of a new drug that Warner-Lambert was developing. Warner-Lambert decided to promote off-label uses of Neuron tin even though off-label promotion is expressly prohibited by the FDA.

Exhibit A at 29.

Further, Dr. King opined in regard to Defendants' failure to adequately disclose to physicians the risks from ingestion of Neurontin for off label uses:

> Warner-Lambert and Pfizer allegedly promoted off-label uses of Neurontin by making false claims about its uses and efficacy. Warner-Lambert and Pfizer allegedly failed to disclose or omitted information about Neurontin's lack of efficacy and its side effects. Both of these actions would have affected the prescribing habits of physicians.

Exhibit A at 24, 25.

Dr. King provides expert opinion critical to demonstrate Defendants' state of mind and their scienter to promote/market Neurontin illegally off-label for uses unapproved by the FDA. Plaintiff requires this expert testimony to prove that Defendants' wanton and reckless conduct was intentional. Dr. Charles King will provide expert testimony on how Defendants knowingly disregarded their duty of care when they illegally promoted Neurontin for off-label uses while at the same time fraudulently concealing/suppression the risks of adverse mood and behavior and an increased risk for suicide.

B. Plaintiff Requests Express Permission to Bring Laptop Computers into the Courtroom for Greater Efficiency

Plaintiff requests express permission from this Court, pursuant to Local Rule 83.02(2) and Judge Trauger's Practice and Procedure Manual V. Trial Procedures (M) Courtroom Technology, to bring computers and electronic media into the courtroom to be utilized during the trial of this action.

Defendants have produced more than three million pages of documents as well as databases comprising several gigabytes of information. Altman Decl. at ¶ 2. For greater efficiency, Plaintiff intends to present evidence during the trial using electronic means. In order to accomplish this, it is necessary for counsel to have computer equipment available in the courtroom. This has been the practice in the two previous Neurontin trials held in the U.S. District Court for the District of Massachusetts. Plaintiff also intends to introduce testimony by video deposition for certain witnesses. This video is played through computer, thus necessitating counsel's use of computers in the courtroom. Furthermore, to fully cross-examine Defendants' witnesses requires that Plaintiff have access to the document repository and full collection of the parties' exhibits (maintained in electronic format on computers) thus necessitating Plaintiff having computers available in the courtroom.

CONCLUSION

Plaintiff respectfully requests that this Court issue an order providing clarification regarding the meaning of a "matter" within Local Rule 39.01(c)(6)(a), granting Plaintiff's request for prior approval to exceed the three-expert witness limitation under Local Rule 39.01(c)(6)(a), and granting Plaintiff express permission to bring computers and electronic media into the courtroom to be utilized during the trial of this action.

Dated: April 16, 2010

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this the 16th day of April, 2010, I electronically filed the foregoing document with the Clerk of the Court, United States District Court for the Middle District of Tennessee, using the CM/ECF system. True and correct copies of the foregoing documents are being served via the Court's CM/ECF system on the following:

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